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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/520,785 | 04/10/2006 | Robert Rohwer | VET-0003 | 2431 |
| 7590 | 05/12/2008 | | | |
| MILLEN, WHITE, ZELANO & BRANIGAN, P.C. Suite 1400 2200 Clarendon Boulevard Arlington, VA 22201 | | | EXAMINER | |
| | | | BOESEN, AGNIESZKA | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1648 | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/520,785 | ROHWER ET AL. |
| | Examiner | Art Unit |
| | Agnieszka Boesen | 1648 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on February 25, 2008.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-36 is/are pending in the application.
 - 4a) Of the above claim(s) 1-20 and 31-36 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 21-30 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/06/08)
Paper No(s)/Mail Date 1/11/2005
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

This Non-Final Office Action is responsive to the communication received February 25, 2008.

Election/Restrictions

Applicant's election with traverse of group II claims 21-33 is acknowledged.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The Office inadvertently included claims 31-33 in group II. Claims 31-33 should have been included in group I because claims 31-33 depend from claims 10, 19, and 20 of group I.

Claims 1-20 and 31-36 are withdrawn because the claims are drawn to the non-elected invention. Claims 21-30 are under examination in this Office Action.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on January 11, 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the Examiner.

Claim Interpretation

Claims are drawn to a method for detecting or isolating a PrP^{res} signal from a sample comprising adding a protease in the presence of detergent to a PrP^{res} containing sample to digest PrP^C present in the sample, denaturing PrP^{res} remaining in the sample, applying the solution to the resin and eluting the PrP^{res} signal from the resin. The recitation of the PrP^{res} signal is interpreted to refer to the PrP^{res} molecule itself. The specification does not provide a definition

for the recitation of the PrP^{res} signal. With regard to the PrP^{res} signal the current specification discloses:

“[0014] This technology allows the concentration of PrP.sup.res signal from extremely dilute solutions, and the selective capture of PrP.sup.res signal from complex protein mixtures in which it is otherwise not detectable due to the presence of interfering substances.”

Thus in the absence of Applicant's definition of a PrP^{res} signal, this recitation is interpreted to mean the detection of the PrP^{res} molecule itself.

It is noted that terms abnormal or pathogenic prion, PrP^{Sc} and the PrP^{res} are used interchangeably in the art, the term PrP^{Sc} refers to the pathogenic scrapie form of prion protein which is a proteinase K resistant - PrP^{res} form of prion protein. Thus the prior art detecting the abnormal or pathogenic prion, PrP^{Sc} and the PrP^{res}, detects the same abnormal prion protein as the PrP^{res} referred to in the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 contains blank spaces. Therefore the scope of the claim cannot be determined. Correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21-23 and 25-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmerr et al. (US Patent 6,150,172).

Schmerr discloses a method for isolating the abnormal pathogenic form of prion protein PrP^{res} comprising adding a proteinase K in the presence of SDS detergent to a PrP^{res} containing sample, denaturing PrP^{res} remaining in the sample by boiling, eluting the PrP^{res} on a Protein A or Protein G resin conjugated to an anti-PrP antibody and performing Western blot after the eluting step (see column 5, lines 59-67, column 8, lines 44-51, column 9, lines 4-21, Examples 1-4).

Thus by this disclosure Schmerr anticipates the present claims.

Claims 21-23 and 27-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Turk et al. (European Journal of Biochemistry, 1988, Vol. 176, p. 21-30).

Turk discloses a method for isolating the abnormal pathogenic form of prion protein PrP^{res} comprising adding a protease in the presence of detergent to a PrP^{res} containing sample, denaturing PrP^{res} remaining in the sample, eluting the PrP^{res} on a Protein A resin conjugated to an anti-PrP antibody and performing Western blot after the eluting step (see the entire document, particularly Materials and Methods and Results).

Thus by this disclosure Turk anticipates the present claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schmerr et al. (US Patent 6,150,172) in alternative with Turk et al. (European Journal of Biochemistry, 1988, Vol. 176, p. 21-30).

Schmerr teaches SDS detergent at 5% and Turk teaches using 2% Triton or Nonidet detergents in their methods of isolating the abnormal pathogenic prion protein from a sample. Turk teaches using 0.1% SDS for Western blot analysis. Neither Schmerr nor Turk teach 0.1% detergent for preparation of pathogenic prion protein for detection or isolation.

However it would have been within the ability of the skilled artisan at the time of the present invention to optimize the concentration of detergent used for preparation of the prion containing sample. It would have been obvious to adjust the concentration of detergent to 0.1% because varying the detergent concentration would have been a routine optimization absent any unexpected results.

Thus the present invention would have been *prima facie* obvious to the person of ordinary skill in the art at the time when the invention was made.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Agnieszka Boesen, Ph.D./
Examiner, Art Unit 1648

/Stacy B Chen/
Primary Examiner, Art Unit 1648